Training Handbook							
Department	TRG	**Project No.**	200102_PHA	**Document No.**	HBK001	**Doc Rev.**	01

Good Laboratory Practice (GLP) Training Handbook PO2015

Presented By Maria Mylonas

How to use this handbook

The handbook is organized to focus on particular skills and revisions.

These lessons allow you to learn and practice the skills used throughout the course.

Table of Contents

1. What is GLP?

Write down your definition.

2. Determining "critical" phases of the study.

What are the "critical" phases of the studies that you are working on?

3. Control of contamination/cross-contamination

We have different levels of control based on the requirements of our different studies. Prevention of contamination is a critical component of quality compliance.

1. Review your work area and list the potential sources of contamination/cross-contamination.
2. What controls do you have in place?
3. Are the controls working or have they failed previously?

Potential source of contamination/ Cross-Contamination	Control Strategy / Mitigation	Working/ Not working

4. Preliminary Hazard Analysis (PHA) – New Analytical Balance

For this activity we will **identify the hazards** associated with the implementation of a new analytical balance.

Consider aspects such as:

- Temperature/humidity
- Personnel
- Calibration
- Maintenance
- Equipment Location
- Power
- Calibration weights

Use the table on the following page to record your answers:

a. In the first column, list the **hazard (potential source of harm)**
b. In the second column, list the **harm (the potential damage caused by the hazard)**
c. In the third column list the **control strategy**

Hazard	Harm	Control Strategy / Mitigation
Cord too long	*Trip hazard. Serious injury*	

5. Risks with SOP Changes

Document some of the risks associated with making changes to SOPs without a change control.

6. Record Review GDocP

For this activity we will identify the **documentation issues** associated with the batch record below and highlight potential risks to product quality.

Tip

Circle all examples of bad documentation practices and provide reasons in this sample batch record.

M.I. NO.	COMPOUNDING INSTRUCTIONS:	
62150	Bovine Medium	
LOT NO.	EFFECTIVE DATE	SUPERSEDES
XXXX -	DRAFT	NEW

PROCEDURE

1. Thaw 1 (one) x 100ml bottle of Fetal Bovine Serum in a water bath set at 37 ± 3 °C for 10 minutes max.

Waterbath ID# WB-001-A — Temp 38 °C

Time in water bath: 7:17 AM/PM — Time out of water bath 7:25 AM/PM

Lot # Fetal Bovine Serum FBS381778 — Date/Time 10 SAN 2014 AM/PM

Performed by SCA

Verified By: PMN — Date/Time ____ AM/PM

2. Prepare three (3) individual bottles of Complete Medium (DMEM, 10% FBS, 1X Glutamax):
Into each 500 mL of DMEM Medium add: 55 ± 5 mL FBS and 50 mg Glutamax

Bottle1	Bottle 2	Bottle 3
FBS added 56 mL	FBS added 60 57 mL	FBS added 58 mL
Glutamax added 50.8 mg	Glutamax added 49.8 mg	Glutamax added 49.5 mg

Lot # FBS RS17-5667 — Lot # Glutamax GLU 44376-00

Balance ID# EQ000-6667 — Calibration date 9-SAN-2014

Date/Time 10 SAN 2014 at 1007 AM/PM — Weight/Volume Verified By ____

3. Label bottles as per SOP-XXX-XXX. Include 14 day expiration date. If not immediately using, store Complete Medium in refrigerator at 4°C ± 2°C.

Bottles labelled as per SOP-XXX-XXX

Fridge ID # FR-67580 Temp 5 °C

Date/time to fridge: 10 SAN 2014 at 12:00 AM/PM — Expiration date (medium): 24 SAN 2013

Verified by: PMN 10 SAN 2014 at 12:00 AM/PM

QA Reviewed By: Joe Barnum 16SAN14

7. FDA Warning Letter Review

Review the warning letter provided.

What were the main issues?

8. Transfer of Learning Plan

Action	Comments
What did you learn today?	
What specifically will you implement from today?	
What do you need to follow up on and learn more about?	
What actions do you need to take to find out more about the topics you wrote above?	

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